

September 15, 2021

COVID-19 Vaccine: Additional mRNA Vaccine Dose for Certain Populations and Medical Exemption Program

The COVID-19 Vaccine Implementation Task Force has announced today a couple of initiatives that will require individuals to have a discussion with a health care provider.

Additional Dose for Certain Populations

Manitoba will begin offering a third dose of an mRNA vaccine to:

- people 12 years of age and older who are moderately to severely immunocompromised due to a medical condition and/or treatment which includes:
 - Active treatment for solid tumor or hematologic malignancies, OR
 - Receipt of solid organ transplant and taking immunosuppressive therapy, OR
 - Receipt of CAR-T therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy), OR
 - Moderate to severe primary immunodeficiency, OR
 - Stage 3 or advanced untreated human immunodeficiency (HIV) infection and those with acquired immunodeficiency syndrome, OR
 - Anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (defined as the equivalent to greater than or equal to 20 mg of prednisone for 4 or more weeks), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) blockers and other biologic agents that are significantly immunosuppressive). For clarity, this includes the following drugs: active treatment with immunosuppressive medications such as cancer chemotherapeutic agents (chemotherapy, immunotherapy or targeted therapies), TNF blockers, certain biologic agents (e.g., rituximab), mycophenolate, tacrolimus, Jak inhibitors, methotrexate, fingolimod, azathioprine and leflunomide.
 - Individuals in end stage renal disease undergoing hemodialysis or peritoneal dialysis, those on the transplant list and people with a ventricular assist device have been shown to be at increased risk of experiencing severe outcomes from COVID-19. There is limited data available on the safety and effectiveness of providing additional doses to these relatively small patient populations. Additional dose recommendations for these patient populations should be made on a case-

by-case basis, taking into account the patient's risks of exposure, level of immunocompromise, risk of experiencing severe outcomes as well as the lack of evidence.

- individuals who wish to receive a third dose for travel purposes; and
- individuals who have received one or two doses of a vaccine that is not approved by Health Canada.

People who are immunocompromised can be immunized by a physician or pharmacist along with a clinical assessment. Those who would like to receive a third dose for travel purposes must go through an informed consent process and be vaccinated by a physician or present a prescription to a pharmacist.

People who have previously received one or two doses of a vaccine not approved by Health Canada can receive one dose of an mRNA vaccine to be considered fully immunized. They can be immunized at supersites, pop-ups or mobile clinics, or by a health care provider. Individuals can have their immunization record updated with the non-Health Canada approved vaccines by following the process outlined at <https://manitoba.ca/covid19/vaccine/immunizationrecord/residents.html#immunization-records>.

In all situations, these doses should be given a minimum of 28 days after the person's most recent dose of any COVID-19 vaccine.

Please refer to the most updated version (version 18 as of September 15, 2021) of the Clinical Practice Guidelines (www.gov.mb.ca/asset_library/en/covidvaccine/clinical_practice_guidelines.pdf) for more information on optimal timing of third doses, as well as information on the risks and benefits for the purposes of informed consent.

Medical Exemption Program

Based on the guidance of the vaccine implementation task force's medical advisory committee, people may be eligible for temporary or permanent medical exemption from the public health orders that restrict access to certain public settings to fully vaccinated persons, as per the following exemption criteria:

- Diagnosis of myocarditis or pericarditis within seven days of an mRNA COVID-19 vaccine, confirmed by a licensed cardiologist.
- Diagnosis of Guillian-Barré syndrome (GBS) within 42 days of COVID-19 vaccination, confirmed by a licensed neurologist.
- A report of a serious adverse event following immunization (AEFI) after a dose of COVID-19 vaccine where a licensed provincial medical officer of health has recommended against further vaccination, confirmed by a licensed provincial medical officer of health.
- Acute diagnosis of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) confirmed by a CancerCare Manitoba (CCMB) hematologist represents an absolute

contraindication to further vaccination with an adenovirus vector COVID-19 vaccine. Subsequent vaccination with an mRNA COVID-19 vaccine may be feasible but should be approved by a CCMB hematologist.

- CAR-T therapy within the last three months, confirmed by CCMB hematologist/oncologist.
- Allogenic or autologous stem cell transplant within the last three months, confirmed by CCMB hematologist/oncologist.
- Solid organ transplant recipients: pre-transplant within two weeks of transplant and post-transplant within the last month regardless of induction therapy, confirmed by the the licensed specialist supervising the transplant.
- Active receipt of anti-cancer drug therapy may attenuate the immune response to vaccination however, given the significant risk of COVID-19 related severe complications and mortality in this patient population, the general approach has been to proceed with immunization. There may be clinical reasons in a subset of this population where deferring vaccination to a later date is appropriate, as per the CCMB licensed oncologist/hematologist.
- Active receipt of one or more of the following medications within the last six months may attenuate the immune response to vaccination: alemtuzumab, anti-thymocyte globulin (ATG)/thymoglobulin, basiliximab, blinatumomab, obinatuamb, ocrelizumab, ofatumumab, cyclophosphamide or rituximab. Given the significant risk of COVID-19 related severe complications and mortality in this patient population, the general approach has been to proceed with immunization. There may be clinical reasons in a subset of this population where deferring vaccination to a later date is appropriate, as per the CCMB oncologist/hematologist or licensed specialist prescribing the therapy.
- Severe allergy or anaphylactic reaction to a previous dose of a COVID-19 vaccine or any of its components that cannot be mitigated, confirmed by a licensed allergist at the Health Sciences Centre (HSC) Allergy Clinic.

Individuals who are eligible may have an existing relationship with a licensed specialist. Patients that self-identify as being contraindicated to COVID-19 vaccination will need to be referred to a licensed specialist, unless they already have a specialist, for assessment of medical exemption eligibility and processing of their application.

The process for specialist physicians to submit medical exemptions will be finalized as soon as possible, and a separate communication is being sent to specialist physicians. The clinical guidance for health care professionals will be updated to provide additional details on the above situations. A notification will be sent out when the updated (version 19 or later) of the Clinical Practice Guidelines are available.

Those who are granted a medical exemption will be able to access the same public services where proof of immunization is required, as those who are vaccinated. More details will be shared in the coming weeks.

There will be no ability to view the medical exemption on eChart.

Factsheets and Clinical Practice Guidelines will be updated to reflect these changes and posted at: <https://www.gov.mb.ca/covid19/vaccine/resources.html> and <https://www.gov.mb.ca/covid19/vaccine/healthcare-professionals.html>.

Please share this information with all relevant colleagues in your facility/clinic.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Reimer', with a horizontal line extending to the right.

Joss Reimer, MD FRCPC MPH
Medical Lead, Vaccine Implementation Task Force